

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

**In re: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION,**

**MDL No. 1456
Master File No. 01-CV-12257-PBS**

THIS DOCUMENT RELATES TO:

Hon. Patti B. Saris

*United States of America ex rel. Ven-A-Care of the
Florida Keys, Inc., et al. v. Dey, Inc., et al., Civil
Action No. 05-11084-PBS,*

Defendants.

**DEY DEFENDANTS' REPLY MEMORANDUM IN FURTHER SUPPORT OF THEIR
MOTION TO DISMISS THE UNITED STATES' AND VEN-A-CARE'S COMPLAINTS**

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PRELIMINARY STATEMENT

Dey submits this reply memorandum in further support of its motion to dismiss the United States Complaint (the “U.S. Complaint” or “U.S. Compl.”) and Plaintiff Ven-A-Care’s Complaint adopting the U.S. Complaint (the “Relator’s 2006 Complaint”). The Government and Ven-A-Care submitted separate answering memoranda (the “U.S. Mem.” and “VAC Mem.” respectively), which Dey addresses below.

I. THE UNITED STATES’ COMPLAINT IS UNTIMELY

In *United States ex rel. Cosens v. The Baylor Univ. Medical Center*, 469 F.3d 263, 268 (2d Cir. 2006), the Second Circuit held that an action under the False Claims Act (or “FCA”) brought by the Government as intervenor is commenced for statute of limitations purposes under 31 U.S.C. § 3731 when the Government’s complaint-in-intervention is filed. The Second Circuit rejected the same tactic that Plaintiffs advance here – that filing the relator’s original *qui tam* complaint somehow grants the Government unlimited time to bring an action against an FCA defendant. *Id.* The Government, moreover, cannot rely on subpoenas, investigative demands, superseded prior pleadings, and meetings prior to service of the complaint (*see* U.S. Mem at 15-16), to give Dey notice in lieu of compliance with Rule 4 of the Federal Rules of Civil Procedure (or “Federal Rules”). Such papers are not the equivalent of the *single* complaint which Rules 3, 4 and 7 of the Federal Rules require to commence an action. The Government seeks to relate back its action to at least seven different pleadings from at least two separate actions. The *Baylor* court’s rejection of the Government’s argument is fully consistent with the First Circuit’s holding that, for limitations purposes, it is essential that the complaint with which the defendant is actually served give fair notice of the claims: “It is the complaint itself which must provide notice.” *O’Loughlin v. National Railroad Passenger Corp.*, 928 F.2d 24 (1st Cir. 1991). The Government refrained from unsealing this action for nine years, which allowed it to take one-

way discovery of Dey. This deprived Dey of the right to take discovery on an equal footing to defend itself. *See U.S. v. St. Joseph's Reg'l Health Center*, 240 F.Supp.2d 882, 893-94 (W.D. Ark. 2002). The Government must live with the consequences of its tactical decisions. *See U.S. ex rel Health Outcome Technologies v. Hallmark Health Systems Inc.*, 409 F.Supp.2d 43, 52 (D. Mass. 2006). The U.S. Complaint is untimely and should be dismissed.

A. The Statute of Limitations Is Not Tolloed By The Filing of Relator's 1997 and 2000 Complaints

The filing of the Relator's complaint in the Southern District of Florida in 1997 (the "1997 Florida Complaint") and a second complaint in the District of Massachusetts in 2000 (the "2000 Massachusetts Complaint") did not "toll" the FCA statute of limitations with respect to the Government. (*Cf.* U.S. Mem., at 6.) No provision in the FCA provides for such a toll. The Government cites none. 31 U.S.C. § 3731(b)(2) is the only tolling provision found in the FCA, and this toll runs three years from when "facts material to the right of action are known or reasonably should have been known" by the appropriate "official of the United States." *Id.* The 3-year tolling provision was added in 1986 at the same time Congress amended the seal provision. *See* S. Rep. 99-345 (1986), *as reprinted in* 1986 U.S.C.C.A.N. 5266, at 5289. Had Congress intended to provide a toll for the United States based on extensions of the seal period, it could have done so. The Order, dated September 9, 2006, unsealing this case (the "September 9 Order"), moreover, authorized service of the United States Complaint. It did not authorize unsealing or service of the 1997 Florida Complaint or the 2000 Massachusetts Complaint. Indeed, the Government's notice of intervention requested that these pleadings remain under

seal.¹ They, therefore, should not be treated as operative pleadings in this case and cannot be relied upon.

The Government argues the action should be deemed “brought” for limitation purposes under § 3731(b) when the Relator filed it. Apparently, an independent action was not brought against Dey in the Southern District of Florida in 1997 (the “Florida Action”); rather, a pre-existing complaint, which Dey was never served, was amended to add Dey as a defendant. (*See* VAC Mem., at 3.) The FCA does not address this procedure and does not define “brought” – so it is not readily apparent what Congress meant. The Government cites district court decisions prior to *Baylor*, such as *U.S. ex rel. Costa v. Baker and Taylor, Inc.*, 1998 WL 230979 (N.D. Cal. 1998) and *U.S. ex rel. Downy v. Corning, Inc.*, 118 F. Supp.2d 1160 (D. N.M. 2000), and argues that its action should be deemed to have been brought when a complaint against Dey was filed, even though no case was meaningfully brought against Dey until it was served in 2006. These decisions rely on the traditional limitation tolling rule under Fed R. Civ. P. 3, which provides that an action is commenced when filed.

Rule 3, however, must be read with Rule 4, which requires that a summons be served within 120 days. *See* Fed. R. Civ. P. 4(m); *see also Defelice & Son, Inc. v. Globe Indemnity Co.*, 23 F.R.D. 275, 278 (S.D.N.Y. 1959). Section 3732(a) of the FCA provides that a summons must be issued pursuant to the Federal Rules; the Government is not excused from complying with the Federal Rules of Civil Procedure in an FCA case. *See Hallmark Health Systems, Inc.*, 409 F. Supp. 2d at 48. As explained in the Advisory Committee Notes to Rule 3,

¹ Copies of the Government’s Notice of Election to Intervene in this case, the September 9 Order unsealing this case, and Ven-A-Care’s Complaint adopting the U.S. Complaint are annexed as Exhibits A, B, and C respectively, to the accompanying Declaration of Neil Merkl in Further Support of Dey Defendants’ Motion to Dismiss (“Merkl Decl.”), dated February 16, 2007. Redacted incomplete copies of pleadings under seal were furnished to Dey’s counsel after commencement of the action; the totality of the court files remains sealed. (*See* Merkl Decl. ¶ 7.)

the “requirement of Rule 4(a) that the clerk shall ‘forthwith issue the summons and deliver it to the marshal for service’” also guards against any prejudice to defendants raising the statute of limitations defense in light of Fed. R. Civ. P. 3 that the filing of a complaint commences the action. *See* Comment 4, Advisory Committee Notes to Fed. R. Civ. P. 3 (1937); *Defelice & Son*, 23 F.R.D. at 278. Indeed, the toll for filing under Rule 3 only applies when Rule 4 is followed and “service is effected within a reasonable time period.” *See Novak v. Nat’l Broadcasting Co., Inc.*, 131 F.R.D. 44, 45 (S.D.N.Y. 1990); *see also* 4C Wright & A. Miller, FEDERAL PRACTICE AND PROCEDURE §§ 1053, 1056 (2d ed 1987). Nine years is not reasonable, and the Government should not be able to benefit from any toll. The Government has offered no reason for the delay and, indeed, continues to withhold the court records reflecting the reasons it presented for keeping the action sealed. This intentional nine year delay between filing the original complaint and serving the United States complaint is itself so prejudicial that it justifies dismissal of the action. *Cf. Sealed Appellant v. Sealed Appellee*, 452 F.3d 415, 418 (5th Cir. 2006) The Second Circuit, therefore, was plainly correct in *Baylor*, when it held that the operative date for statute of limitations purposes was when the Government’s complaint-in-intervention was filed, which was the only pleading served on the defendants.

None of the Government’s cases, moreover, address delays of 9 to 10 years to pursue claims that are 15 years or more old, nor do they address the interplay of Fed. R. Civ. P. 3 and 4. The Government, citing *Downy*, argues that running the statute of limitations from the time the U.S. Complaint was filed is incompatible with the FCA’s seal provision, and that following *Baylor* would undermine the policy behind the seal provision by compelling the Government to act too quickly. (*See* U.S. Mem., at 11). There is no genuine conflict with the seal period and the *Baylor* holding because the 3-year tolling extension Congress provided in §

3731(b)(2) more than adequately protects the Government. Assuming the Government knew nothing of the claims until the Relator delivered the complaint, 31 U.S.C. § 3731(b)(2) would still leave the Government three years within which to extend the seal within the limitations period. This also is in keeping with Congress' understanding that the 60-day seal period ordinarily would furnish the Government sufficient time to evaluate a case: "[k]eeping the *qui tam* complaint under seal for the initial 60 day time period is intended to allow the Government an adequate opportunity to fully evaluate the private enforcement suit..." See S. Rep. 99-345, 1986 U.S.C.C.A.N. 5266, at 5289. Congress did not intend to allow the Government to "unnecessarily delay." *Id.* Viewed this way, the 3-year toll reflects Congress' balance of the need for more time to investigate in unusual circumstances against the defendants' legitimate rights that the 6-year limitations period protects:

Statutes of limitations are primarily designed to assure fairness to defendants. Such statutes "promote justice by preventing surprises through the revival of claims that have been allowed to slumber until evidence has been lost, memories have faded, and witnesses have disappeared."

Hallmark Health Systems, 409 F. Supp. 2d at 52 (quoting *Burnett v. New York Central R.R. Co.*, 380 U.S. 424, 428 (1965)).

Allowing the unlimited toll demanded by the Government, on the other hand, invites abuse of the seal procedure since the Government may, on grounds entirely hidden from the target of the investigation, obtain multiple seal period extensions, wait indefinitely, and allow alleged false claims to accumulate before finally deciding to pursue its claims against the defendant. The Government can also take discovery under other powers without the defendant having the same right or opportunity to preserve evidence. Congress did not intend that defendants would be prejudiced by the seal period: "By providing for sealed complaints, the

Committee does not intend to affect defendants' rights in any way." S. Rep. 99-345, 1986 U.S.C.C.A.N. at 5289.

Congress observed that the "initial 60-day sealing of the allegations has the same effect as if the *qui tam* relator had brought his information to the Government and notified the Government of his intent to sue," and that extension requests be "carefully scrutinized" to avoid any "unnecessary delay." *See id.* The seal was not intended to relieve the Government of its obligation to act with diligence. *See, e.g., U.S. v. Stella Perez*, 956 F. Supp. 1046, 1052 (D. Puerto Rico 1997) (the FCA statute of limitations "imposes a duty of diligence on the part of the government to ascertain facts material to its right of action"). Under the Plaintiffs' logic, not even the 10-year statute of repose could curtail the time limit of the Government's action. The toll that the Government asks this Court to find – based on the seal provision – would eviscerate the statute of limitations, completely contrary to the intention of Congress. *See, e.g., U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 726 (10th Cir. 2006).

The Government's reliance on *U.S. v. Maling*, 737 F. Supp. 684 (D. Mass. 1990), is entirely misplaced. The sealed indictment cases in fact support Dey's position that the Government's action was not tolled by the filing of the Relator's Complaint given the Government's 9 year delay in intervening and unsealing its claims. In *Upton*, this Court dismissed an indictment that had been sealed for only one year and two months on statute of limitations grounds, because the Government's delay in unsealing the indictment and arresting the defendants was unreasonable, and therefore the statute of limitations was not tolled. *See United States v. Upton*, 339 F. Supp.2d 190, 195-196 (D. Mass. 2004) (Saris, J.). Thus, while a sealed indictment may toll a statute of limitations, the toll may be lifted, and the statute is deemed to run, if the Government unreasonably delays in unsealing the indictment. *Id.*, at 196

(“[t]o allow the Government to extend the statute of limitations...would undermine the role which statutes of limitations have traditionally served”).

There is also nothing in the *Rivera* decision that would permit the Government to hold Dey in “perpetual liability.” (See U.S. Mem., at 10; *see also* Dey Defendants’ Memorandum of Law In Support of Their Motion to Dismiss The United States’ Complaint (“Dey’s Mem.”), at 13-15.) Unlike here, the *Rivera* defendants controlled the extent of their own liability and the intermediary in that case did not file multiple claims for payment over a 15-year span based on the same alleged false statement. *See U.S. v. Rivera*, 55 F.3d 703 (1st Cir. 2003). Indeed, the Government’s position is completely at odds with the Supreme Court’s ruling in *Bornstein* – which the Government conveniently fails to address – that the FCA should “penalize[] a person for his own acts, not for the acts of someone else.” *See U.S. v. Bornstein*, 423 U.S. 303, 313 (1976).

B. The United States’ Complaint Does Not Relate Back To the Relator’s Complaint

It would be fundamentally unfair to allow relation back under Rule 15 to a pleading that was never timely served on Dey. *See Baldwin County Welcome Center v. Brown*, 466 U.S. 147 (1984) (the “rationale of Rule 15(c) is that a party who has been notified of litigation concerning a particular occurrence has been given all the notice that statutes of limitations were intended to provide”). The Second Circuit held that relation back would not be permitted under Fed. R. Civ. P. 15(c)(2) because defendants never received adequate and timely notice. *See Baylor*, 469 F.3d at 269-70.

The Government argues that pursuant to Fed. R. Civ. P. 15(c)(1), the FCA authorizes relation back. (U.S. Mem., at 11). However, the Second Circuit considered this argument, citing *Downy*, and declined to apply it. Moreover, Rule 15(c)(1) does not apply

because the FCA does not contain its own relation back provision. *See Edwards v. First American Title Ins. Co. of Nev.*, 1994 WL 102402, *5 (1st Cir. 1994) (Rule 15(c)(1) is inapplicable where “[n]one of the statutes of limitations which may possibly apply to any of [plaintiffs’] claims contain such a provision [allowing relation back]”). As Point I(A) demonstrates, nothing in the legislative history suggests that Congress intended to create a relation back doctrine in the scheme of the FCA that would prejudice a defendant and effectively nullify the statute of limitations. Rule 15(c)(1) has mainly been applied where a state relation back rule conflicts with the relation back rule in Rule 15(c). *See* 6 James W. Moore *et al.*, MOORE’S FEDERAL PRACTICE § 15.20 (3d ed. 1999), at 15-103. The Government’s only basis for inferring relation back under Rule 15(c)(1) is that the FCA contains a statutory seal period. (U.S. Mem., at 12.) Inferring a rule of relation back under Rule 15(c)(1) is inconsistent with Congress’ stated intention that the seal not “affect” the defendant’s rights and its conclusion that 60 days ordinarily would be sufficient; it also conflicts with the Federal Rules, which require service within a reasonable time after filing the complaint in order to obtain a toll under Rule 3.

The Government also contends *Baylor* should not be followed because unlike Rule 15(c)(3), which expressly requires notice, there is no notice requirement under Rule 15(c)(2) as long as the Government’s complaint is based on the same “conduct, transaction, and occurrences” as the relator’s complaint filed under seal. (*See* U.S. Mem., at 16.) The Government’s position ignores the reality that in every other situation under Rule 15(c)(2), the defendant has already been served and is in the case.

In addition, relation back should not be permitted under Rule 15(c)(1) and no toll should be allowed for the reasons explained in *St. Joseph’s Regional Health Center*. The court held that the Government’s actions in using the seal for tactical litigation advantages over a 10

year period – under circumstances remarkably similar to those here – amounted to an abuse of the seal process which warranted a refusal to allow relation back to the original complaint:

The essential nature of the False Claims Act, which is to allow a private plaintiff to assert on behalf of the government fraud claims about which the government is uninformed; to allow a reasonable time for the government to investigate and then to give the government its choice to carry on with the case or leave it to the relator. Contrary to that plan, the multiple interventions in this case appear to the Court to have no other justification than to allow the government to investigate and settle the multiple claims at its own pace, selectively carving out those claims that were easiest to settle while keeping the remaining defendants in limbo until it chose to act against them.

St. Joseph's Regional Health Center, 240 F. Supp. at 888. *Accord Hallmark Health Systems*, 409 F. Supp. 2d at 49-50.

C. The U.S. Complaint Cannot Relate Back Because the Prior Pleadings Are Inadequate Placeholders

A “relation back” rule would not help the Government here because the Government has not – and cannot – establish the validity of the prior pleadings and proceedings on which it seeks to rely. *See Biby v. Kansas City Life Ins. Co.*, 629 F.2d 1289, 1294 (8th Cir. 1980). In *Baylor*, the Court held that if relation back were allowed it would have to confront the “substantial question” whether the original complaint was adequate:

If grossly insufficient complaints are deemed sufficient to support relation-back for a complaint-in-intervention filed by the government, and if the government’s “good cause” for delay is its need to get done what would have been done if the relator’s complaint had been minimally sufficient, the FCA’s statute of limitations may fail to serve its purpose.

Baylor, 469 F.3d at 270 n.10. In *Hallmark Health*, this court refused to allow relation back to a prior complaint where the venue for the original complaint was improper. *See Hallmark Health Systems*, 409 F. Supp. 2d at 49-50. The prior pleadings filed by Ven-A-Care are also inadequate placeholders for the reasons set forth below.

1. Prior Proceedings In This Case Were Barred by 31 U.S.C. § 3730(b)(5)

It is the Plaintiffs' burden to allege and prove subject matter jurisdiction.

Viqueira v. First Bank, 140 F.3d 12, 18 (1st Cir. 1998). Since the Government seeks to relate its complaint back to the 1997 Florida Complaint and the 2000 Massachusetts Complaint, it must, therefore, allege and establish that the courts originally had subject matter jurisdiction over the complaints as filed. The U.S. Complaint makes no such allegation.

The first stumbling block to subject matter jurisdiction over the prior complaints is 31 U.S.C. § 3730(b)(5), which provides that “[w]hen a person brings an action under this subsection [*i.e.*, the Relator’s Florida Action], no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.” 31 U.S.C. § 3730(b)(5). This bar divests the court of subject matter jurisdiction over subsequent related actions brought by anyone other than the Government. *See U.S. ex rel. Ortega v. Columbia Health Care*, 240 F. Supp. 2d 8, 11 (D.D.C. 2003). Section 3730(e)(3) also barred Ven-A-Care from commencing a subsequent action. If this Court gives any present effect to the 1997 Florida Complaint, then there would have been no jurisdiction over the Massachusetts action commenced in 2000 (the “2000 Massachusetts Action”) while the Florida Action was pending.² All proceedings in this Court, therefore, would have been barred by 31 U.S.C. §§ 3730(b)(5) and 3730(e)(3), including the transfer to this Court and the joinder of the 1997 Florida Action. To avoid this result, this action must be deemed to have commenced on the date the U.S. Complaint was filed in this Court in 2006.

² The 2000 Massachusetts Action was undeniably a related action brought by a person “other than the Government” because it was brought by Ven-A-Care. The Government concedes that the 2000 Massachusetts Action raises the “same core facts and legal theories” as the 1997 Florida Action (U.S. Mem., at 15). This Court, therefore, never had subject matter jurisdiction over the 2000 Massachusetts Action; and if relation back is allowed to the 1997 Florida Action, the Court may not have it now.

In addition, as Point V(B) below demonstrates, the facts on which the 1997 Florida Complaint against Dey relies were publicly disclosed in 1996, and the U.S. Complaint does not allege that Ven-A-Care was an original source of the claims against Dey. This failure would have divested the Florida District Court of jurisdiction under 31 U.S.C. § 3730(b)(5).

2. The Government Cannot Use “Relation Back” To Sealed Proceedings

Fed. R. Civ. P. 5 requires the Government to serve all orders and pleadings and prior papers in the action on Dey. If the U.S. Complaint relates back to the 1997 Florida Complaint, which it does not, the Government has failed to make such service or disclosures, and instead has maintained that they remain sealed. It is incompatible with due process for the Government to base its relation back theory on earlier *ex parte* proceedings withheld from Dey. *Hallmark Health Systems, Inc.*, 409 F.Supp.2d at 52 (the “government’s *ex parte* actions will not now be left unchallenged in a court that enjoys the benefit of an adversary proceeding in order to give deference to judgments made by a court that did not”). Since the Government has declined to unseal the prior proceedings, it cannot rely on them. Dey is entitled to examine the complete record and test the Government’s claim of “good cause” on which extensions were granted under 31 U.S.C. § 3730(b)(3), and whether the multiple amended complaints on which Plaintiffs rely were properly granted under Rule 15. If the extensions for the seal were granted without good cause, or the amended pleadings violated the Federal Rules, they cannot be used to toll the limitations period against Dey. *See St. Joseph’s Reg’l*, 240 F.Supp.2d at 888. Dey should be permitted to challenge the Government’s assertion of “good cause” (*see* 31 U.S.C. § 3730(b)(3)) to keep the action under seal in the same way Dey may challenge Fed. R. Civ. P. 4(m) request for extensions of the 120-day period for service. *Cf. Riverdale Mills Corp. v. U.S. Dept. of Transp.*, 225 F.R.D. 393 (D. Mass 2005). Dey should not be held to *ex parte* rulings that undermine its rights.

II. **THE REBATE AGREEMENT BARS THE GOVERNMENT'S COMMON LAW AND FCA CLAIMS**

The Rebate Agreement and 42 U.S.C. § 1396r-8³ define the “actual price paid” for the manufacturer’s drugs and require that they be reported as AMP, rather than as AWP or WAC. The Government contends that “Dey could have just reported one number both (1) as its AMP to the Medicaid drug rebate program and (2) to the pricing compendia relied upon by Medicare and Medicaid to set reimbursement levels.” (U.S. Mem., at 21.) However, there is no rule or law requiring it, and the Government cites none. There is no legal reason why Dey could not continue to report both the AMP and follow the preexisting industry practice of reporting AWP and WAC that differ from AMP. The Government’s claim conflicts directly with its agreement with Dey that actual costs including discounts be reported as AMP under confidentiality arrangements provided by statute.

The Government contends that this action has nothing to do with the Rebate Agreement or AMPs because the action is based on Dey’s failure to report true AWP and WACs. But, each of the Government’s claims rests on the allegation that Dey’s AWP and WACs should have been equivalent to Dey’s AMP (*see* Compl. ¶ 51; *see also* U.S. Mem., at 21), which is specifically and contractually defined as the “*average unit price paid to the Manufacturer...by wholesalers for drugs distributed to the retail pharmacy*” and “*includes cash discounts allowed and all other price reductions...which reduce the actual price paid.*” (Rebate Agreement, § I(a) (emphasis added).)

The Government’s claim for unjust enrichment, therefore, directly conflicts with the express terms of the Rebate Agreement which require the “actual prices paid” for Dey’s

³ This section was amended in the Deficit Reduction Act of 2005. All citations to § 1396r-8 in this brief refer to the version that was effective prior to the passage of the Deficit Reduction Act of 2005.

drugs to be reported as AMP. The Rebate Agreement bars the Government's unjust enrichment claim because the Government agreed that Dey would report what the U.S. Complaint refers to as "actual costs" as AMP rather than AWP or WAC. (U.S. Compl., ¶ 51.) It cannot rewrite the terms of the Rebate Agreement. *See, e.g., Micromuse, Inc. v. Micromuse, PLC*, 304 F. Supp. 2d 202, 209 n.8 (D. Mass. 2004); *U.S. v. EER Systems Corp.*, 950 F. Supp. 130, 133 (D. Md. 1996).

The Rebate Agreement also establishes that it was unreasonable as a matter of law for the Government to rely on AWP or WAC as actual prices when the Government knew and agreed that actual prices including discounts would be called AMP. *See Trifiro v. New York Life Ins. Co.*, 845 F.2d 30, 33 (1st Cir. 1988) ("When a person acts in a way contrary to his [or her] own acknowledged understanding of the facts, his [or her] acts must be deemed unreasonable as a matter of law."). The Government cites this Court's decision in *Mylan* out of context in contending that it was "not required to 'reverse engineer' Dey's AMPs every quarter [to] compare them to Dey's false reported prices and then take corrective action...." (*See* U.S. Mem., at 22.) In *Mylan*, the Court only held that a state Medicaid agency was not required to "reverse engineer" URAs into AMPs. *See Massachusetts v. Mylan Labs.*, 357 F. Supp. 2d 314, 323 (D. Mass. 2005). In this case, Dey provided the Government with the actual AMPs (rather than merely URAs). (*See* U.S. Mem., at 19.) Thus, no "reverse engineering" was required. To the extent the Government is now contending that the Rebate Agreement cannot bar the state Medicaid fraud claims because the states did not have access to AMPs during the relevant time period, this contention is beside the point. First, this action is brought by the Government; the Government claims that the Government itself was injured. Second, the Government concedes that "state Medicaid programs are required to develop reimbursement formulas that must be *approved by the Secretary of HHS.*" (U.S. Mem., at 39-40 (emphasis added).)

Contrary to the Government's assertions, the Rebate Agreement is a contract. The U.S. Complaint alleges that suppliers must "agree" to participate in the Medicaid program. (See U.S. Compl. ¶ 23.) The Rebate Agreement is that "agreement." A statutorily required contract confers contractual rights when the contract was executed on behalf of the state, and the terms of the contract exceed those required by the statute. See *Hollander v. Brezenoff*, 787 F.2d 834, 838 (2d Cir. 1986); *Nat'l R.R. Passenger Corp. v. Atchison, Topeka and Santa Fe Ry. Co.*, 470 U.S. 451, 466 (1985). The Rebate Agreement was executed "on behalf of the Department of Health and Human Services and all States and the District of Columbia..." (See Rebate Agreement, at p. 1.) Moreover, the Agreement does not simply mirror 42 U.S.C. § 1396r-8, but provides a definition of AMP more specific than the definition Congress provided in § 1396r-8(k)(1). Compare Rebate Agreement § I(a) with 42 U.S.C. § 1396r-8(k)(1) (2000). In addition, the Rebate Agreement provides contractual remedies to both the Government and Dey that are not expressly defined by § 1396r-8. See Rebate Agreement §§ V, IV, VIII(c). Thus, that the statute requires a written agreement does not alter the fact that Dey and the Government entered into a contract governing pharmaceutical price reporting.

The Government's cited cases are inapposite because they involve questions as to whether Medicare provider agreements gave rise to a contractual interest in Medicare payments or simply to a statutory entitlement⁴ – an issue which is not present in this action – or questions as to other government entitlements which are inapplicable here.⁵ The only case the Government cites discussing rebates in the Medicaid prescription drug program does not address whether

⁴ See, e.g., *Memorial Hosp. v. Heckler*, 706 F.2d 1130, 1136 (11th Cir. 1983).

⁵ See, e.g., *See Bowen v. Public Agencies Opposed To Social Security Entrapment*, 477 U.S. 41, 51-52 (1986) (extending federal retirement benefits to state employees); *National R.R. Passenger*, 470 U.S. at 467 (railroads' entitlement to be free from their passenger service obligations to the Government).

Medicaid rebate agreements with HCFA are contracts.⁶ The Government cites to no case which holds that the Rebate Agreement at issue is not a contract.

III. THE GOVERNMENT HAS NOT SATISFIED RULE 9(b)

The Government argues that the holding of *U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004), requiring an FCA plaintiff to identify and plead specific details as to the allegedly false claims submitted, applies only to the Relator, and not to the Government. The Government can cite no case in support. Cases brought by the Government are equally dismissed when the Government fails to satisfy Rule 9(b). *See, e.g., Hallmark Health Systems, Inc.*, 409 F. Supp.2d at 53 (applying *Karvelas* to dismiss FCA claims brought by the Government under Rule 9(b)); *see also U.S. v. Henderson*, No. 03-0506 (MJD/JDL) 2004 WL 540278 (D. Minn. March 16, 2004); *U.S. v. Cheng*, 184 F.R.D. 399 (D. N.M. 1998). Dey, moreover, has not asked for the minutiae of “every single detail” of thousands of claims. (*See, e.g., U.S. Mem.*, at 26.) Dey’s point is that the Government has not identified even *one* concrete claim it paid that it can tie to a concrete misrepresentation allegedly made by Dey. Referring to a “J” code is not sufficient because a “J” code can refer to a manufacturer other than Dey.

The Government also contends that a relaxed pleading standard somehow applies because the information needed to fill the gaps of its own defective complaint is in its own hands. (*See, e.g., U.S. Mem.*, at 26-27.) Again, the First Circuit recognizes no such exception based on who possesses the requisite information. *See, e.g., Karvelas*, 360 F.3d at 233-35. The Government’s failure to plead with specificity the submission of any false claim is even more troubling in this case because it does not – and cannot – allege that Dey itself “presented” or

⁶ *See Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652 (2003).

submitted any false claims for reimbursement. Furthermore, with respect to alleged Medicaid overpayments, the Government still has not clarified, as it must, whether it seeks only the federal share, or whether it seeks both the federal and state shares.

IV. THE U.S. COMPLAINT DOES NOT STATE A CLAIM FOR RELIEF

A. The Government Has Not Alleged the Essential Elements of Its FCA Claims

1. The Government Has Not Alleged Falsity

The U.S. Complaint does not allege falsity because it fails to allege either (i) that Dey's reporting of AWP's and WAC's violated a controlling rule, regulation or standard, or (ii) that Dey itself misrepresented what it reported as its AWP's and WAC's. (*See* Dey's Mem., at 29-30.) None of the cases cited by the Government dispenses with this requirement. *See, e.g., Cook County v. U.S. ex rel. Chandler*, 538 U.S. 119, 124 (2003) (falsity based on defendant's violation of express conditions of federal grant); *U.S. v. Neifert-White Co.*, 390 U.S. 228, 229 (1968) (falsified application to federal agency for a loan).

In this case, there is no federal statute, rule or regulation, and the Government can point to none, that requires Dey to report AWP's or WAC's. *See U.S. ex rel. Mayman v. Martin Marietta Corp.*, 894 F. Supp. 218, 225 (D. Md. 1995) (“[t]here is no freestanding duty to provide accurate information to the Government” and “[t]o the extent a duty exists in this case, it comes from the federal regulations...”). In contrast, the court in *Rivera* found falsity because, unlike here, defendants transmitted false invoices to a federal agency through an innocent third-party and falsified documentation in violation of various criminal statutes and regulations. *See Rivera*, 55 F.3d at 706. The Government's references to collusive bid-rigging schemes are also inapposite because, apart from that fact that such schemes are anticompetitive, “[t]he bidding itself was a federal requirement” in those cases and the bidders “certified that their bids were

‘genuine and not sham or collusive.’” *U.S. ex rel. Marcus v. Hess*, 317 U.S. 537, 543 (1943); *Murray & Sorrenson v. U.S.*, 207 F.2d 119, 121-22 (1st Cir. 1953) (same).⁷

2. Government Knowledge Precludes a Finding of Falsity and *Scienter*

Contrary to the Government’s contention, knowledge is not only a defense to *scienter*, but can negate the falsity element under the FCA. *See U.S. ex rel. A+ Homecare, Inc. v. Medshares Mgmt. Group, Inc.*, 400 F.3d 428, 445 (6th Cir. 2005) (if “plaintiff cannot show that the government agency would have acted differently had it known of the omission, ‘there is no *false* claim because [the agency’s action] would have occurred regardless of [defendant’s] actions’”). Similarly, since the Government knew Dey’s AWP for albuterol differed from what the Providers were paying, there can be no “false” claim. The Government knew AWP differed from acquisition costs, but paid them anyway.⁸

The Government concedes that the audit reports demonstrate that the “reported prices deviated in significant fashion from the actual prices.” (U.S. Mem., at 31.) However, the Government alleges that state Medicaid programs – and Medicare until 2005 – continued to pay on a reimbursement system based on these reported prices. (*See* U.S. Compl. ¶ 50.) Indeed, the audit reports surveyed the AWP as to the very same multi-source drug – *i.e.*, albuterol – that is alleged in the U.S. Complaint and reported a “spread” in 1996 of over 200%. (*See* Robben Decl., Ex. I, at 6.) The FCA does not permit the Government to turn a blind eye and later recoup whatever it claims it lost through its own willful blindness or acquiescence. *See Mikes v. Straus*,

⁷ The Government’s citation to *In re Lupron* is also unavailing, as the court merely assessed the sufficiency of the plaintiff’s mail and wire fraud allegations as predicate acts for the civil RICO claim. *See In re Lupron Marketing and Sales Practices Litig.*, 295 F. Supp. 2d 148, 167-68 (D. Mass. 2003). Moreover, the court held that the complaint did not satisfy 9(b) by relying “on generic assertions that marketing, sales, and other documents were disseminated by mail and wire.” *Id.*, at 169; (*see also, supra*, Point III.)

⁸ The Government has not addressed any of the cases cited by Dey on this point. (*See* Dey’s Memo, at 31-32.)

274 F.3d 687, 697 (2d Cir. 2001) (since the FCA is “restitutionary and aimed at retrieving ill-begotten funds, it would be anomalous to find liability when the alleged noncompliance would not have influenced the government’s decision to pay”).

3. The Government Failed to Allege Causation Under the FCA

The Government’s attempted analogy to *Rivera* (see U.S. Mem., at 33) breaks down at the first step, because by falsifying requests for loans from the intermediary, entitling the latter to payment of that same amount from the Government under an insurance arrangement procured by the defendants, the *Rivera* defendants effectively controlled the nuts and bolts of the false claims process. In order for the *Rivera* analogy to apply here, the Providers would need to unfailingly bill the same amount that they paid for Dey’s products. However, the crux of the Government’s claim is that the Government paid the Providers more than the Providers paid for Dey’s products.

Moreover, the Government’s failure to even allege that Dey had any degree of participation in the Providers’ claims process is fatal to its case.⁹ (See Dey’s Mem., at 33-34.) Even in *Parke-Davis*, this Court required a *minimum* showing that the defendant’s conduct be a “substantial factor” in causing the presentation of false claims. See *U.S. ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255, *5-6 (D. Mass. Aug. 22, 2003). The Government has not alleged, other than in conclusory fashion, whether and to what extent Dey’s reporting of AWP’s and WACs or any alleged marketing of the “spread” was a “substantial factor” in the submission

⁹ The Government’s reliance on *Zimmer* and *Scolnick* is unavailing. In *Zimmer*, the court found causation satisfied because defendants entered into contracts with and furnished illegal kickbacks to physicians, inducing the latter to file false certifications and obtain reimbursements for services furnished under prohibited self-referrals. *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3rd Cir. 2004). Tellingly, the court also held that “mere awareness” of another’s filing of false claims does not amount to causation. *Id.*, at 245; *Scolnick v. United States*, 331 F.2d 598, 599 (1st Cir. 1964) (defendant “presented” false claim by depositing government check known by defendant to have been issued by mistake).

of alleged false claims by Providers. The Government has not alleged what it would have actually reimbursed Providers during the time period in question if Dey did not report AWP or WACs. Nor can the Government allege that the Medicare and Medicaid programs reimbursed Providers on the basis of Dey's AWP or WACs to support a finding of proximate causation.¹⁰

B. The Government Cannot Rely on the Anti-Kickback Statute As Predicate for Violation of the FCA Without Alleging Illegal Remuneration

The Government also cannot premise FCA liability here under an alleged violation of the Anti-Kickback Statute (or "AKS") because there is no kickback or illegal remuneration.¹¹ Indeed, "illegal remuneration" under the AKS cannot mean alleged overpayments that the Government knowingly, or even mistakenly, furnished to the Providers, and no case supports the untenable hypothesis that any alleged overpayment by the Government to Providers in this case constitutes "illegal remuneration" under the AKS.¹² Further, the Government has not and cannot allege that any such payments by the Government to the Providers were "illegal," in light of numerous audit reports establishing that the Government knew and approved of such payments in order to adequately compensate Providers and

¹⁰ The U.S. Complaint concedes that Medicare reimbursement was based on the "median" AWP for all generic forms of the drug, and that Medicaid reimbursement was based on the "lowest" of the EAC, provider's usual and customary charge, MAC and FUL. (See U.S. Compl. ¶¶ 38, 45-47.)

¹¹ Also, the U.S. Complaint nowhere alleges that Dey either directly or indirectly provided any illegal remuneration to Providers. The Government's contention here should thereby be dismissed because it cannot amend the U.S. Complaint's deficiencies via a brief in opposition to a motion to dismiss. *McGrath v. MacDonald*, 853 F. Supp. 1, 2-3 (D. Mass. 1994).

¹² Rather, in all of the cases the Government relies on here, payments by the defendants were conditioned upon some form of illegal referrals. See, e.g., *U.S. ex rel. McNutt v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1258 (11th Cir. 2005); *U.S. ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 614 (N.D. Ill. 2003); see also; *Schmidt*, 386 F.3d at 239; *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 901 n.1 (5th Cir. 1997); *U.S. ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc.*, 238 F. Supp. 2d 258, 261 (D.D.C. 2002); *U.S. v. Greber*, 760 F.2d 68, 71 (3rd Cir. 1985); *U.S. v. Bay State Ambulance and Hosp. Rental Serv., Inc.*, 874 F.2d 20, 27 (1st Cir. 1989).

encourage Provider participation in the Medicaid and Medicare programs. (*See, e.g.*, Robben Decl., Exs. H – L.)

The Government is also wrong that it need not allege any single federal certification because in “an implied certification context, by its very name, liability is found even in the absence of an express certification.” An “implied false certification is appropriately applied *only when* the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid.” *See U.S. ex rel. Mikes v. Straus*, 274 F.3d 687, 700 (2d Cir. 2001) (emphasis added). The Government can point to no case where implied certification has ever been applied to Medicaid claims. *See id.*, at 699 (“False Claims Act was not designed for use as a blunt instrument to enforce compliance with all medical regulations”). The Government also cannot prevail under an “implied certification theory” for Medicare claims because the Government cannot allege that it would not have paid the claim had it known of the violation. *See, e.g., Bidani*, 264 F. Supp.2d at 615; (*see also* Dey’s Mem., at 36-37.)

C. The Government Fails To State its Claims For Unjust Enrichment

The unjust enrichment count should be dismissed because it is premised on the same underlying “wrong” alleged for Counts I, II and IV.¹³ *See Guyana Tel. & Tel. Co. v. Melbourne Int’l Comms., Ltd.*, 329 F.3d 1241, 1245 n.3 (11th Cir. 2003); *In re Lupron*, 295 F. Supp. 2d at 182 n.38. The government also alleges a benefit far too remote from the alleged detriment. An essential element of unjust enrichment claim is a “relation between the

¹³ The Court’s decision in *In re Pharm. Average Wholesale Price Litigation*, 339 F. Supp. 2d 165, 181 (D. Mass. 2004), does not apply here. There, the plaintiff sued manufacturers for underpaying Best Prices rebates to a New York county, in violation of the clear terms of the manufacturer’s rebate agreements with the state (but not the county). No such allegation is made here and thus the quoted portion of that decision is pure *dicta*. Further, the Court’s decision involved interpretation of New York unjust enrichment law, which no one suggests applies here. *See, e.g., In re Lupron*, 295 F. Supp. 2d at 182 (five elements of unjust enrichment under Massachusetts law include “absence of a remedy provided by law”).

enrichment and impoverishment.” *In re Lupron*, 295 F. Supp. 2d at 182. The Government cannot allege this element because whatever alleged “market shares” or profits Dey obtained did not derive from the Government, and whatever alleged overpayments or “spread” the Government paid was not furnished to or retained by Dey, but rather by the Providers. The Government argues that the “payments from the government flowed to Dey’s customers, who in turn paid Dey for the drugs, generating profits for Dey.” This is the very definition of “remote.” *See Rapaport v. U.S. Dep’t Treasury*, 59 F.3d 212, 217 (D.C. Cir. 1995)(indirect benefit accruing to defendant in the form of higher stock earnings too remote); *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 936-37 (3d Cir. 1999) (relationship between profits to tobacco companies and losses to insurers of cigarette smokers too remote for a finding of unjust enrichment).

D. The U.S. Complaint Does Not State a Claim for Common Law Fraud

The Government’s allegations of reliance in the context of Medicaid reimbursement address only reliance by the states, who are not parties in this action. Reliance by the Government cannot be inferred from the nature of the Medicaid program or the Government’s approval of state reimbursement plans. *See In re Pharmaceutical Industry Average Wholesale Price Litig.*, 339 F. Supp. 2d at 180.

The Government also fails to properly allege that its reliance, if any, was reasonable. Reliance is unreasonable as a matter of law when the alleged reliance “is contrary to his [or her] own acknowledged understanding of the facts”. *Trifiro v. New York Life Ins. Co.*, 845 F.2d 30, 33 (1st Cir. 1988). The Government acknowledged in the Rebate Agreement that actual costs, including discounts, would be represented by AMP rather than AWP or WAC. Moreover, the audit reports establish that it would have been unreasonable for the Government to rely on AWP as representative of actual costs.

V. VEN-A-CARE'S COMPLAINT ALSO MUST BE DISMISSED

A. As An Assignee of the United States' Claims, Ven-A-Care is Subject to the Same Defenses as the United States

Since the United States is barred from pursuing the claims in this action, so too is Ven-A-Care. Ven-A-Care cites no authority allowing it to proceed in the absence of the Government after the Government intervenes. *U.S. ex rel. Sarmont v. Target Corp.*, No. 02-C-0815, 2003 U.S. Dist. LEXIS 18729 (N.D. Ill. Oct. 17, 2003) is irrelevant because Ven-A-Care has asserted no claims on its own behalf. Rather, it seeks to enforce claims on behalf of the United States. The FCA provisions the Relator relies on apply only if the Government elects not to proceed. *See* 31 U.S.C. §§ 3730(b)(4)(B) and 3730(c)(3). No FCA provision allows the Relator to take over if the Government's case is lost after the Government intervenes. Moreover, the time for the Relator to complain about the Government's "protracted investigation" was 1997. (*See* VAC Mem., at 5.) The Relator could have opposed the Government's multiple requests for the seal period extension in court.

A *qui tam* relator, such as Ven-A-Care, has Article III standing to sue only as an assignee of a claim belonging to the United States. *See Vermont Agency of Natural Resources v. U.S. ex rel. Stevens*, 529 U.S. 765, 773 (2000). All Ven-A-Care does in the unsealed action, moreover, is adopt the U.S. Complaint. (*See* Relator's 2006 Complaint, at ¶ 2; Merkl Decl., Ex. C.) As an assignee of the United States' claims, Ven-A-Care is subject to the same defenses as the United States. In *U.S. ex rel. Barajas v. Northrop Corp.*, 147 F.3d 905 (9th Cir. 1998), the Ninth Circuit affirmed dismissal of a relator's *qui tam* complaint because the relator's claims arose from "same transactional nucleus of fact" as the claims the United States settled with the defendant:

[The relator] could not have a claim separate from the government's. A *qui tam* relator has Article III standing to sue only as a relator, on behalf of

the government. His standing is in the nature of an assignee of the government's claim. Thus, there is one claim, the government's, pursuable either by the *qui tam* relator on behalf of the government, or by the government on its own behalf.

Northrop Corp., 147 F.3d at 910 (internal citations omitted).

The Relator's contention that the Second Circuit in *Baylor* "did not have the benefit of the subsequent decision of the United States Supreme Court" in *B.P. Am. Prod. Co. v. Burton*, 549 U.S. ___, 2006 U.S. LEXIS 9586 (2006), is beside the point. (See VAC Mem., at 6) The *Burton* holding that the 6-year limitations period under 28 U.S.C. §2415 was not applicable to an "administrative proceeding," is entirely consistent with the view that where Congress has expressly set forth a statute of limitations, that limitations period applies equally to a relator as well as to the Government.¹⁴

B. The Court Does Not Have Subject Matter Jurisdiction That Would Allow Ven-A-Care to Assert Claims Independent of the Government

Neither the Relator's 2006 Complaint nor the U.S. Complaint allege an independent basis for subject matter jurisdiction based on Ven-A-Care as the Relator under the FCA. Allegations contained in previous *qui tam* complaints filed by Ven-A-Care in this action cannot save the U.S. Complaint – and by extension, Ven-A-Care's Complaint – because allegations and claims raised in an original pleading but not set forth in a subsequent pleading are waived. See *Kolling v. American Power Conversion Corp.*, 347 F.3d 11, 16 (1st Cir. 2003) ("[a plaintiff's] amended complaint completely supersedes his original complaint, and thus the original complaint no longer performs any function in this case.") Even if this Court did refer to previous pleadings filed in this action, they would not allow jurisdiction over Ven-A-Care's

¹⁴ *Burton* and the other tax assessment/administrative proceeding cases cited by Plaintiffs are further unavailing to their case because the Government contends that Rule 3 should apply to the FCA, in which case the Plaintiffs were required under Rule 4 to effect service within a reasonable time. The Government cannot have it both ways.

present claims. The prior pleadings provided by the Government to Dey's counsel are heavily redacted and in large part unintelligible. The unredacted portions of those pleadings fail to allege with any specificity how Ven-A-Care gained knowledge of the specific conduct alleged against Dey or what specific information – original or otherwise – Ven-A-Care provided to the Government before commencing this action.

FCA section 3730(e)(4)(A) provides that “[n]o court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a ...Government Accounting Office report, hearing, audit, or investigation...unless...the person bringing the action is an original source of the information.” Although the government may be immune from an “original source” defense, the Relator is not. *See U.S. ex rel. O’Keefe v. Sverdup Corp.* 131 F. Supp.2d 87 (D. Mass. 2001) (Saris, J.) (dismissing relator’s *qui tam* action because it was based on publicly disclosed information of which the relator was not an original source). An action is “based on” publicly disclosed information if it is “substantially” similar to information that gave the government sufficient notice of the claims. *Id.*, at 96.

The 1996 audit reports issued by the Office of Inspector General referenced in Dey’s original brief confirm that the Government, through its own investigative efforts, knew that published AWP’s for albuterol did not equal providers’ “actual acquisition cost” for that drug in 1996, more than a year before Dey was named as a defendant in the Relator’s *qui tam* action. (*See* Dey’s Mem., at 10-11.) The 1996 audit report identifies one year earlier the same 200% or more “spread” for albuterol (*see* Robben Decl., Ex. I, at 6) that is also alleged in the 1997 Florida Complaint. (*See* Merkl Decl., Ex. D, at p. 47) The information contained in the OIG Reports has been “publicly disclosed.” *See U.S. ex rel. Feingold v. Adminastar Federal Inc.*, 324 F.3d 492 (7th Cir. 2002).

The U.S. Complaint does not allege facts demonstrating that Ven-A-Care was the “original source” of the information contained in the audit reports, and fails to meet the basic pleading requirements concerning jurisdiction contained in Fed. R. Civ. P. 8. Since the U.S. Complaint should be dismissed, the Court does not have jurisdiction over claims asserted by Ven-A-Care.

CONCLUSION

For the foregoing reasons, Dey respectfully requests that the Court dismiss the United States’ and Ven-A-Care’s Complaints, with prejudice, and grant Dey such other, further, and different relief as the Court deems to be just and proper.

Respectfully submitted,

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Dated: February 16, 2007

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on February 16, 2007, a copy to LexisNexis File & Serve for posting and notification to all parties.

_____/s Neil Merkl